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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,899	01/28/2004	Jan Berka	21465-508 UTIL	6163
35437	7590	08/25/2006	EXAMINER	
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO 666 THIRD AVENUE NEW YORK, NY 10017			THOMAS, DAVID C	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/767,899	Applicant(s) BERKA ET AL.	
	Examiner David C. Thomas	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, 22, and 24-34, drawn to methods for amplifying one or more nucleic acids, classified in class 435, subclass 91.2.
 - II. Claims 16-21, drawn to a library comprising a plurality of nucleic acid molecules immobilized to a bead, classified in class 536, subclass 23.1.
 - III. Claims 34-38, drawn to methods for producing a clonal population of proteins, classified in class 435, subclass 68.1.
 - IV. Claims 23 and 39-44, drawn to an emulsion comprising microreactors, and a kit comprising nucleic acid capture beads, and emulsion oil, and one or more emulsion stabilizers, classified in class 435, subclass 287.2.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions in Groups II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group I, drawn to methods for amplifying one or more nucleic acids, can be practiced by any number of materially products, such as the products in Groups II or products comprising combinations of different types capture beads or sources of nucleic acid molecules other than libraries, such as restriction digests or PCR products of genomic DNAs.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, searching the inventions of Group I and Group II would impose a serious search burden. The inventions of Group I and Group II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods for amplifying one or more nucleic acids and products comprising libraries is not coextensive.

5. Inventions in Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group III, drawn to methods for producing a clonal population of proteins, can be practiced by any number of materially different products, such as the products in Group II or other products comprising combinations of different types capture beads or sources of nucleic acid molecules other than libraries, such as restriction digests or PCR products of genomic DNAs.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, searching the inventions of Group II and Groups III would impose a serious search

burden. The inventions of Group II and Groups III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods for producing a clonal population of proteins and products comprising libraries, and nucleic acid capture beads, is not coextensive.

7. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention in Group I is drawn to methods for amplifying one or more nucleic acids, while the invention in Group III is drawn to methods for producing a clonal population of proteins. These methods have different modes of operation since the nucleic acid methods utilize nucleic acid templates to produce more nucleic acid molecules, while the methods of protein production utilize nucleic acid templates to produce polypeptides. Furthermore, the nucleic acids and proteins represent structurally different molecules with different chemical characteristics, different methods of making and using and different functions and effects.

8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper.

9. Inventions in Groups IV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case Group I, drawn to methods for amplifying one or more nucleic acids, can be practiced by any number of materially products, such as the kits and products in Group IV or products comprising combinations of different types of capture beads, emulsions, and emulsion stabilizers.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, searching the inventions of Group I and Group IV would impose a serious search burden. The inventions of Group I and Group IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods for amplifying one or more nucleic acids and kits and products comprising microreactors, emulsion oils and nucleic acid beads is not coextensive.

11. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention in Group II is drawn to a library comprising a plurality of nucleic acid molecules immobilized to a bead, while the invention in Group IV is drawn to an emulsion comprising microreactors, and a kit comprising nucleic acid capture beads, and emulsion oil, and one or more emulsion stabilizers. These methods have different modes of operation since the library comprising a plurality of nucleic acid molecules immobilized to a bead is used as a template for amplifying nucleic acids, while the emulsion comprising microreactors contains beads but also other reagents to

perform the amplification process. Furthermore, the nucleic acids and oil emulsions represent structurally different molecules with different chemical characteristics, different methods of making and using and different functions and effects.

12. Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Group II, restriction for examination purposes as indicated is proper.

13. Inventions in Groups IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group III, drawn to methods for producing a clonal population of proteins, can be practiced by any number of materially different products, such as the kits and products in Group IV or products comprising combinations of different types of capture beads, emulsions, and emulsion stabilizers.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, searching the inventions of Group III and Group IV would impose a serious search burden. The inventions of Group III and Group IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods for producing a clonal population of proteins and kits and products comprising

microreactors, nucleic acid capture beads, emulsion oil, and one or more emulsion stabilizers is not coextensive.

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

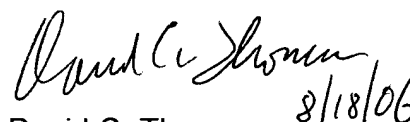
17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320. The examiner can normally be reached on 5 days, 9-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David C. Thomas
Patent Examiner
Art Unit 1637



JEFFREY FREDMAN
PRIMARY EXAMINER

8/18/06

JEFFREY FREDMAN
PRIMARY EXAMINER